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smiths

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SECTION 5, 510(k) Summary

Company Information:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene, NH 03431
(603) 352-3812, prompt 4, ext 2493
Contact: Brian D. Farias
Regulatory Affairs Manager

Summary Prepared: December 18, 2006

Product Name:

Trade Name: **Portex® Hypodermic Needle-Pro® Fixed Needle Syringe**

Common Name: Fixed Needle Hypodermic Syringe with attached needle protection

Classification Name: 880.5860 Piston Syringe with Single Lumen Needle with antistick

Predicate Device(s):

K024249 (Terumo Medical Corporation) Terumo SurGuard™ Insulin, Allergy and General Use Safety Syringe and alternate brand name Portex® Hypodermic Needle-Pro® Fixed Needle Syringe (referred to as the "Terumo SurGuard™ Safety Syringe" throughout the remainder of this submission).

Please note that the attached needle protection (brand name Needle-Pro®) of the predicate device is supplied to Terumo Medical Corporation by Smiths Medical. Smiths Medical holds a 510(k) for this device, K011925. The needle protection component of the proposed device is essentially the same as that cleared above except it is made from a different polypropylene.

Device Description:

The Portex® Hypodermic Needle-Pro® Fixed Needle Syringe is a graduated hypodermic syringe with a permanently affixed needle and integral needle safety sheath. The safety sheath rotates so it can be adjusted to the desired position relative to the needle bevel and syringe graduations. The syringe is used to inject fluids into the body. The Insulin syringe barrel is graduated in U-100 Insulin units and the TB syringe is graduated in milliliters (ml). After the procedure is completed, the needle is pressed into the sheath using a one-handed technique. The needle enters the protective sheath and is contained within the sheath. The device is then discarded into a sharps container.

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Indications for Use:

This device is intended for aspiration and injection of fluids including Insulin. The needle protection device covers the needle after use to help prevent needle sticks.
[See pages 9 and 10 for the specific indication for Insulin and TB (General Use) syringes]

Technological Characteristics:

The proposed and predicate devices have a permanently affixed needle and a hinged style protective sheath that is manually activated after use.

Non-Clinical Data:

Bench testing confirms that the proposed device and the predicate device have similar performance specifications based on the applicable standards for this device and FDA guidance for devices with sharps injury prevention features.

Clinical Data:

Simulated clinical use studies were conducted for Insulin and TB syringes which confirmed that the device could be used effectively with the needle shielded inside the protection device after use.

Conclusion:

The bench testing and simulated clinical use studies conducted demonstrate that the proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Brian D. Farias
Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Brian D. Farias
Regulatory Affairs Manager
Smiths Medical ASD, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431

FEB 27 2007

Re: K063755
Trade/Device Name: Portex® Hypodermic Needle-Pro® Fixed Needle TB Syringe, Portex® Hypodermic Needle-Pro® Fixed Needle Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: December 18, 2006
Received: December 19, 2006

Dear Mr. Farias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

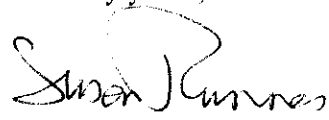
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4B, Indications for Use Statement

Indications for Use

510(k) Number (if known): K063755

Device Name: **Portex® Hypodermic Needle-Pro® Fixed Needle TB Syringe**

Indications for Use:

This device is intended for aspiration and injection of fluids. The needle protection device covers the needle after use to help prevent needle sticks.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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SECTION 4A, Indications for Use Statement

Indications for Use

510(k) Number (if known): K063755

Device Name: **Portex® Hypodermic Needle-Pro® Fixed Needle Insulin Syringe**

Indications for Use:

This device is intended for aspiration and injection of U-100 Insulin Only. The needle protection device covers the needle after use to help prevent needle sticks.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use __X__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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